

### **Remarks**

Claims 1-3, 5, 15-27, 54-56, 59-61, 63, 65-67, and 69 have been rejected by the Examiner. Claims 4, 6-14, 28-53, 57, 58, 64 and 71-74 have been provisional withdrawn from consideration. Claims 2, 3, 28-61, 63-67, 69 and 71-74 have been cancelled. Claims 62, 68 and 70 have been indicated as containing allowable subject matter. Claims 1, 19, 62, 68 and 70 have been amended. New claims 75 and 76 have been added. Reconsideration and allowance are respectfully solicited.

#### **I. Election/Restriction**

The Examiner has required Applicant to elect a single disclosed species for prosecution on the merits if no generic claim is finally held to be allowable. Applicant's counsel made a provisional election during a phone conference with the Examiner and now confirms Applicant's provisional election to prosecute Group A, Species I, Group B, Species II, claims 1, 5, 15-27, 68, and 70, as well as new claims 75 and 76.

Applicant requests reconsideration of the restriction requirement that was made in connection with Species I-XI in group B. The mere fact that each claimed system may require a different component does not alone render each species independent and distinct. To be sure, the Examiner makes no showing that searching and examining these species would place a serious burden upon the Examiner, as required by M.P.E.P. 803, nor is this believe to be the case.

**II. Claim Objection**

Claims 68 and 70 have been objected to by the Examiner because the phrase "the display" lacks antecedent basis. The Examiner has indicated that the claims would be allowable if rewritten in independent form. Applicant has amended the claims to provide an antecedent basis for "the display" and rewritten the claims in independent form. The claims are now believed to be in condition for allowance.

**III. Rejection of Claims Under 35 U.S.C 101**

The Examiner has rejected claim 11 under 35 U.S.C 101 for claiming non-statutory subject matter; the Examiner stated that the phrase "external to the body" in the claim has a positive relationship to the body. Applicant did not find this phrase in claim 11 and claim 11 has in any event provisionally been withdrawn. However, claims 19 and 43 do contain the phrase "external to the patient." Claim 43 has been cancelled and claim 19 has been amended to instead state "external to the implantable housing." Claim 19 is therefore believed to be in compliance with requirements of 35 U.S.C. 101.

**IV. Rejection of Claims Under 35 U.S.C 102(b)**

The Examiner has rejected claims 1, 3, 15, 18, 21, 23, 27, 54, 55, 56, 63, 65, 66, 67, and 69 under 35 U.S.C 102 (b) as being anticipated by Miesel et al. (US 6,106,477).

Claim 1 has been amended to include additional limitations, including those in claim 3, and claim 3 has been cancelled. As amended, Claim 1 recites a system for monitoring tissue condition comprising: a housing configured to be implanted between a first tissue and a different second tissue within a patient's body, the housing including a first surface located on a first outer side of the housing configured to rest against the first tissue, and a second surface located on a second outer side of the housing, opposite from the first outer side, configured to rest against the second tissue; a first sensing system proximate to the first surface configured to sense a physiological property of the first tissue; a second sensing system proximate to the second surface configured to sense the same physiological property of the second tissue proximate; and a processing system in communication with the first and second sensing systems configured to compute a difference between the physiological property sensed by the first and second sensing systems.

Amended claim 1 requires a housing that is configured to be implanted between a first tissue and a different second tissue. The housing has a first outer surface that is configured to rest against the first tissue and a second outer surface that is configured to rest against the second tissue which is different from the first tissue. The claim as amended requires the second outer surface to be opposite from the first outer surface. A first and a second sensing system must be proximate to each surface and sense the same physiological property of the two different tissues. No new matter has been introduced. Support for the new

features are provided in paragraphs 28-30 and Figures 1C and 1D of the specification.

Miesel et al. do not anticipate Claim 1. Miesel et al. disclose an implantable device 81 with a probe 85 that encircles a vessel 84 (see Fig 12). The various embodiments utilize a tubular-shaped probe having a slit through which the vessel is inserted into a lumen of the tubular-shaped probe, such as is shown in figures 1-4. Sensors are located within the lumen of the tubular-shaped probe to monitor the vessel that is placed within the lumen.

Miesel et al. do not teach a housing that is configured to be implanted between a first tissue and a different second tissue wherein one outer surface rests against the first tissue and a second outer surface rests against the other tissue different than the first tissue, all as required by claim 1.

On page 6 lines 11-12 of the office action, the Examiner States that "Regarding Claim 3, Meisel '477 further discloses that the sensing surfaces may be on substantially opposite sides of the device (Figure 1)." Miesel et al. do disclose placing sensors at positions 113 and 114 on opposite sides of the fixture (lumen) or the vessels as shown in FIG. 14. See Column 8, lines 18-20 ("Alternatively, these sensor locations can be adjusted to be on opposite sides of the fixture and the vessel, for example at points 113 and 114."). However, these sensors measure the same tissue (i.e. a vessel), not different tissues as required by claim 1. They are also on the interior of the housing 10, not the outside of the housing, as also required by claim 1.

Miesel et al. therefore do not anticipate claim 1. Claims 15, 18, 21, 23, 27 depend from claim 1 and thus are also not anticipated by Miesel et al. Claims 3, 54-56, 63, 65-67 and 69 have been cancelled.

The Examiner has rejected claims 1, 2, 18-20, 22, 54-56, 65-67, and 69 under 35 U.S.C 102(a) as being anticipated by Fitz (US 2002/0183629).

Applicant respectfully requests reconsideration of these rejections.

Fitz does not anticipate amended claim 1. Fitz discloses a probe 20 with two tentacle-like sensors 17 and 18 protruding from the probe, each configured to be inserted into tissue to obtain a differential measurement such as absolute pressure. In paragraph 43, Fitz states: "In the preferred embodiment shown in FIG. 1, the first sensor 17 and second sensor 18 connect to a single housing assembly 20." However, Fitz does not specify that the sensors 17 and 18 are located on opposite sides of the housing assembly 20, as now required by claim 1. To the contrary, Figure 1 shows the two sensors emerging from the same side of the housing assembly 20. Even the Examiner notes on Page 8 of the Office Action that both sensors are "connected to a lower surface" (emphasis added).

Fitz also fails to teach other elements of claim 1. For example, Fritz does not disclose a housing that is configured to be implanted between a first tissue and a different second tissue with a first outer surface that is configured to rest against the first tissue and a second outer surface opposite to the first surface that is configured to rest against the second tissue.

Also unlike claim 1, Fitz's housing assembly is not configured to rest against and between tissue. Rather, Fitz is concerned with the placement of protruding sensors. For example, in paragraphs 51 and 52, Fitz states:

[T]he first and second sensors 17, 18 are connected to the connectors 27, 28. The housing assembly 20 is subcutaneously implanted in, for example, the back using surgical techniques known in the medical art. Those skilled in the art will recognize a wide variety of potential catheter, sheath, or needle designs that could be used to facilitate introduction of the sensors 17, 18 into the aneurysm sac 16 and/or the artery 12.

As clearly reflected by this quoted paragraph, Fitz is not concerned with the position of the implantable housing. To the contrary, Fitz states that a wide variety of potential catheter, sheath, or needle designs could be used to facilitate the introduction of the sensors 17 and 18. It is the extended sensors 17 and 18 that are important; not having opposing surfaces of a housing rest against different tissues, all as required by amended claim 1 of the instant application.

Therefore, claim 1 is allowable over Fitz. Claims 18-20 and 22 depend from claim 1 and thus are also not anticipated by Fitz. Claims 2, 54-56, 65-67, and 69 have been cancelled.

The Examiner has rejected claims 1, 5, 16-18, 20, 22, 24-27, 54-55, 59-61, 63, and 65-67 under 35 U.S.C 102 (b) as being anticipated by Sun et al. (US 6,122,536).

Sun et al. disclose a probe similar to that of Meisel et al. A sensor assembly 14 is tubular in shape and is configured to surround a vessel 20, as shown in Fig. 2. See also column 10, lines 1-3 ("Sensor assembly 14 . . . has an opening which enables it to be arranged to substantially surround a blood vessel 20.").

In the various embodiments of assembly 14, the sensors 30, 32, and 34 are disposed to measure the vessel 20 when placed within the lumen of 14, as shown in FIGs 3 and 4. An alternative form of the sensor assembly 58 "sandwiches" a portion of the vessel, as shown in FIGS. 6 to 11. See column 12, lines 44-49 ("a portion of a vascular membrane such as the parietal peritoneum 52 (shown in phantom in FIG. 6) is sandwiched between two halves 54 and 56 of an alternate form 58 of sensor assembly. Halves 54 and 56 are essentially mirror images of each other, and define a gap 60 between them, which receives the peritoneal tissue "). Unlike what is required by claim 1, therefore, Sun et al. do not disclose sensors on the outside of a housing.

Claim 1 also requires the sensors to measure a parameter of different tissues. Sun et al's probe (like Miesel's) measures a parameter of the same tissue – a vessel.

Claim 1 is therefore not anticipated by Sun et al. Claims 5, 16-18, 20, 22, and 24-27 depend on claim 1 and thus are also not anticipated by Sun et al. Claims 54-55, 59-63, and 65-67 have been cancelled.

**V. Rejection of Claims Under 35 U.S.C 103(a)**

The Examiner has rejected claims 19, 20, 22, 24, 25, and 59-61 as being obvious under 35 USC 103(a) over Miesel et al. in view of Gord et al. (US 5,999,848) or Hines et al. (US 6,582,365).

Claims 19, 20, 22, 24, and 25 all depend upon claim 1. As explained above, claim 1 is not anticipated by Miesel et al. Neither Gord nor Hines remedy any of these deficiencies. Thus, the cited references do not teach all of the limitations of claims 19, 20, 22, 24, and 25 and thus cannot render them obvious. See M.P.E.P. 2143 ("To establish a prima facie case of obviousness, . . . the prior art reference (or references when combined) must teach or suggest all the claim limitations.") Claims 59-61 have been cancelled.

**VI. Allowable Subject Matter**

The Examiner has indicated the claims 62, 68 and 70 would be allowable if rewritten in independent form. Applicant has rewritten the claims in independent form. Claims 62, 68 and 70 are now believed to be allowable.

**VII. New Claims**

New claims 75 and 76 have been added. Dependent system claim 75 is directed to subject matter that was deemed allowable by the Examiner with respect to method claims 62, 68 and 70. Claim 76 is directed to an embodiment depicted in original figures 1C and 1D and is also supported by original paragraphs 28-30.

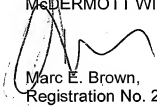


**Conclusion**

Applicant respectfully submits that the above remarks place this application in a condition for allowance, which the Applicant respectfully solicits.

A petition for a three-month extension of time under 37 C.F.C. 1.136 is being filed contemporaneously herewith. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 501946 and please credit any excess fees to such deposit account and reference attorney docket no. 64693-94.

Respectfully submitted,  
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